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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,912	09/11/2007	Austen John Woolfe	TEVE-132US	1400

23122 7590 12/29/2009

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EXAMINER	
ZISKA, SUZANNE E	
ART UNIT	PAPER NUMBER
1619	
MAIL DATE	DELIVERY MODE
12/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,912	WOOLFE ET AL.	
	Examiner	Art Unit	
	SUZANNE ZISKA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 1-24 are pending and examined in this Office Action.

Priority

The instant application is a US National Stage application of PCT/US05/001423. However, it is noted that a certified copy of the priority document does not appear in the application file despite the transmittal letter statement that a copy has been communicated by the IB.

Information Disclosure Statement

No IDS has been filed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spireas (USPN 7,056,951) [Spireas].

Spireas discloses a pharmaceutical composition comprising gabapentin which is substantially free of the corresponding lactam. Spireas discloses the formulations are sufficiently stable upon storage even in the presence of electronegative ions greater than 20 ppm. Spireas discloses that the compounds are stable in the presence of anions from a mineral acid (see, for example, column 2, lines 48-55).

Spireas discloses testing a pharmaceutical composition comprising gabapentin. See, for example, column 14. Spireas discloses the tests were conducted at 40°C/75% RH for 3 months and that the lactam level was less than 0.1%. If the rate of degradation is constant, then one of ordinary skill would have had a reasonable expectation of success in producing a pharmaceutical composition having a lactam level of less than 0.5% w/w after 6 months, lacking evidence to the contrary (claim 4).

Regarding claims 1-3, one of ordinary skill would be able to determine the lactam levels occurring the claimed storage periods. One of ordinary skill would have had a reasonable expectation of success in obtaining the claimed lactam levels under the claimed storage conditions, in view of the teachings of Spireas, disclosing that the conditions for obtaining a lactam level of less than 0.5% can

be determined by routine methods after routine optimization of the composition components. See, for example, columns 8-17.

All the claimed elements herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Furthermore, the optimization of the pharmaceutical formulation with ingredients well known in the pharmaceutical art is considered well within the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 1980).

Regarding claim 5, Spireas discloses the pharmaceutical composition may contain excipients such as microcrystalline cellulose (claims 5, 6 and 9). Spireas discloses a diluent is one type of excipient and teaches microcrystalline as both a diluent and excipient (claim 12).

Spireas discloses the term "excipient" includes such agents such as lubricants, diluents, pigments, binders, colorants (column 6, lines 56-60) (claim 8).

Spireas discloses the lubricant is magnesium stearate (claims 10 and 13), thus disclosing magnesium stearate and microcrystalline cellulose as excipients (column 7, lines 3-5) (claim 7).

Regarding claim 14, Spireas discloses microcrystalline cellulose as a diluent and magnesium stearate as a lubricant, as discussed above. It would have been obvious to substitute sodium lauryl sulphate for the magnesium stearate as a matter of routine optimization because both are considered to be lubricants (claim 11).

Regarding claims 15 and 16, Spireas discloses the formulations can be processed into a stable solid dosage form such as tablets, and hard shell

gelation capsules. The solid dosage forms are for oral use, lacking evidence to the contrary.

Regarding claims 20-24, Spireas discloses the electronegative ions are anions from mineral acids and that preferably the anion is Cl^- and is present in an amount of more than about 20 ppm, thus suggesting that the stability of gabapentin is independent of the mineral acid anion content (claim 18) since no upper limit is taught or suggested. Thus, Spireas teaches a mineral acid anion content of less than 70 ppm (claim 19); a content of less than 50 ppm (claim 20); a content of less than 30 ppm (claim 21); a content range of 20 to 70 ppm (claim 22); a content range of 20 to 50 ppm (claim 23) and a content range of 20 to 30 ppm (claim 24).

Spireas differs from the claims in that the document fails to disclose the specifically claimed colorants or methyl hydroxyl benzoate or propyl hydroxyl benzoate. However, Spireas does disclose that the excipients include "colorants" and therefore the gabapentin composition can comprise the claimed colorants titanium oxide, yellow iron oxide and red iron oxide. It would have been obvious to one of ordinary skill to use any colorant, since the choice of any colorant is a matter of routine optimization, lacking evidence to the contrary (claim 17).

In light of the foregoing discussion, the claimed subject matter would have been obvious with the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole is *prima facie* obvious to one of skill in the art at the time the claimed invention was made, as evidenced by the references.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE ZISKA whose telephone number

is 571-272-8997. The examiner can normally be reached on Monday through Friday 9 AM to 5 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZANNE ZISKA, Ph.D., JD/
Examiner, Art Unit 1619

/YVONNE L. EYLER/
Supervisory Patent Examiner, Art Unit 1619